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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,445	06/21/2001	Robert H. Frater	P 279185 P95US1	2733

909 7590 07/25/2003
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EXAMINER

FERKO, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 07/25/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,445

Applicant(s)

FRATER ET AL.

Examiner

Kathryn Ferko

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 34-124 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-33, 125 and 126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated June 20, 2003. Claims 22-33, 125 and 126 are pending. Amendments to the specification and drawings are acknowledged and accepted.

Response to Arguments

1. Applicant's arguments with respect to the rejection(s) of claim(s) 23-33 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Venegas in US Patent No. 5,074,297.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 23-28 and 125 are rejected under 35 U.S.C. 102(b)/103(a) as being anticipated by Venegas in US Patent No. 5,047,297.

Venegas discloses a mask (10) for delivering breathable gas to a patient where the mask (10) has a shell (16) having a portion adapted to receive a supply of pressurized breathable gas and a user side, recited in column 1, lines 50-67; a cushion (12, 26) constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; headgear (22)

constructed and arranged to attach the mask shell to the user, as stated in column 1, lines 50-67 and seen in figures 1 and 2; a gusset portion (14) having a first side attached to the user side of the shell, as seen in figure 1; and a mask that is a nasal mask, as seen in figure 1.

A gusset portion that is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell and the cushion where, the gusset portion defines a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force $F_{sub.c}$ of the cushion on the user's face, the force $F_{sub.c}$ being maintained in approximately constant proportion to the supply of pressurized breathable gas and a total force of the mask on the face F_m being maintained within a range of about 35-108 grams per $gf/cm.^{sup.2}$ pressure of the supply of pressurized breathable gas over an operating pressure range of the mask; a force F_m that is maintained within a range of about 40-88 grams per $gf/cm.^{sup.2}$ pressure of the supply of pressurized breathable gas; a force F_m that is maintained within a range of about 50-88 grams per $gf/cm.^{sup.2}$ pressure of the supply of pressurized breathable gas; and an operating pressure range that is about 4-25 $gf/cm.^{sup.2}$, are within the scope of the invention and given the structure the system of Venegas would be fully capable of operating within the pressure ranges as claimed.

Further, expansion and contraction of the gusset portion that permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face is also within the scope of the invention as seen in figures 1-4. Venegas also discloses a gusset portion (14) that includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas, as recited in columns 2-4 and seen in figures 1-4.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venegas in US Patent No. 5,074,297.

Although not explicitly recited, a gusset portion that includes a sidewall having a thickened cross-section at a base of the sidewall, where the thickened cross-section has a generally uniform thickness; and a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion are also within the scope of the invention, see column 3, lines 10-50. Therefore, it would be obvious to one with ordinary skill in

the art to provide the gusset portion to have a sidewall having a thickened cross-section at a base of the sidewall, where the thickened cross-section has a generally uniform thickness; and a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion for the purpose of a proper seal.

Further, element 16 of Venegas acts as a generally rigid backstop of the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion extends around substantially an entire periphery of the gusset portion.

Additionally, it is within the scope of the invention to use the mask as a CPAP mask.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as US 2003/0089372 and US 2003/0075180.

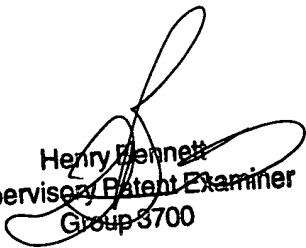
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
July 21, 2003



Henry Bennett
Supervisory Patent Examiner
Group 3700